



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

7/2

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/036,066 | 11/07/2001 | Scott L. Diamond | 3936-011568 | 3883 |

7590 08/26/2005

Barbara E. Johnson
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1818

EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,066

Applicant(s)

DIAMOND, SCOTT L.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12, the preamble claims the "subcomponents", but claim 10, from which claim 12 depends, claims an "assay system". It is unclear as to what Applicant is claiming in claim 12, the assay system, or the components.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Tisone, 5,738,728.

Tisone discloses an assay system comprising :

Art Unit: 1641

a set of operating instructions resident in computer software (col. 7, line 57);

a set of computer-controlled dot applicators (i.e., dispensing apparatus, col. 7, lines 44-45, col. 3, lines 15-26);

a computer-controlled device for sample aerosol generation (col. 4, lines 23-29);

a computer-controlled xy positioner (col. 3, lines 15-19, and col. 7, lines 44-46);

a computer and operating software (col. 7, line 57); and

a chamber for control of biological samples (col. 4, lines 23-25),

wherein dot applicators are capable of creating reaction spots to which aerosolized sample droplets are applied for computer-enhanced assay of any reaction between the sample droplets and the dot constituents (col. 3, lines 19-23.)

As to claim 11, said operating instructions send signals, via serial or parallel port, to start, to stop, to establish operating set points and to control subcomponents of the device (col. 7, lines 56-59.)

As to claim 12, the device further comprises multiple positive displacement microsyringe pumps (col. 5, lines 55-59, and aerosol generating devices (col. 4, lines 23-29.)

As to claim 13, the microsyringes hold 1.0 microliters to 1000 uL of biological sample (col. 5, lines 65-66).

As to claim 14, the microsyringes deliver samples at a constant flow rate (col. 4, lines 66-67.)

Claims 10, 11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by French et al., 5,345,079.

French et al. discloses an assay system comprising :

- a set of operating instructions resident in computer software (col. 4, lines 11-15);

- a set of computer-controlled dot applicators (micropumps or nebulizers col. 17, lines 3-7, and col. 12, lines 52-53);

- a computer-controlled device for sample aerosol generation (col. 4, lines 11-15, and col. 17, lines 3-7);

- a computer-controlled xy positioner (col. 4, lines 10-12);

- a computer and operating software (col. 4, lines 10-12); and

- a chamber for control of biological samples (i.e., nozzles, col. 12, line 52),

wherein dot applicators are capable of creating reaction spots to which aerosolized sample droplets are applied for computer-enhanced assay of any reaction between the sample droplets and the dot constituents.

As to claim 11, said operating instructions send signals, via serial or parallel port, to start, to stop, to establish operating set points and to control subcomponents of the device (col. 12, line 52.)

As to claim 15, the aerosol generation is an ultrasonic nebulizer (col. 17, line 6.)

Response to Arguments

Applicant's arguments filed May 31, 2005 have been fully considered but they are not persuasive. Applicant argues that neither Tisone does not teach nor suggest application of a sample in aerosolized form, or a device to accomplish aerosolization. Applicant also argues that French et al. teaches injection of a sample into a gas stream, but not in any way for the purpose of contacting the sample onto a substrate bearing reaction spots.

In response, the Office notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

In this case, Tisone and French et al. teach the structural limitations of the claimed invention, as described in the rejections above. Moreover, the inventions of Tisone and French et al. are capable of performing the intended use of contacting an aerosolized sample onto reaction spots. Thus, the prior art structure meets the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

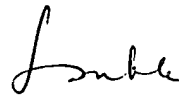
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

6/22/05